K093379

BL Healthcare Inc

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirement of 21 CFR 807.92

Submitter: Michael Mathur
BL Healthcare, Inc
33 Commercial Street, Suite #3
Foxboro, MA 02035
Phone: (508) 543-4150 Fax: (508) 543-6150

FEB - 9 2010

Contact Person: Michael Mathur
President and CEO
Mmathur@BLHealthcare.com

Date Prepared: 10 Oct 2009

Regulation Number: Section 876.5860
Regulation Name: High Permeability Hemodialysis System
Regulatory Class: II
Product Code: KDI
Trade Name: TCx-I-DV Remote Care Management system
Common Name: Telemedicine systems

Legally Marketed Predicate Device(s):
BL Healthcare Remote Care Management system **(K051470)**
Telephone Based TCx-I-DV Remote Care Management system (RCMS) **(K052608)**
MedApps' Remote Patient Monitoring System **(K062377)**
Exalis software 1.15 **(K083158)**

Submission Device Description:
TCx-I-DV Remote Care Management system collects and transmits measurement information such as weight, blood pressure and pulse rate, and dialysis data from the patients on completion of their testing and transmit these results to their healthcare provider at another facility.

Intended use and indications for use:
The **TCx-I-DV Remote Care Management system** is for use by patients remotely in combination with a variety of monitoring devices such as blood pressure monitor, NxStage System One Hemo Dialysis system and weight scale upon the prescription of a licensed physician or healthcare provider. The TCx-I-DV Remote Care Management system serves as the communication link between the compatible devices and the server software at a compatible healthcare facility. The healthcare facility may include healthcare provider, other caregivers, or a disease management center.

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The purpose of the system is to collect and transmit medical information such as weight, blood pressure and pulse rate, and dialysis data from the patients on completion of their testing and transmit these results to their healthcare provider at another facility.

This system is installed by or with support from trained professionals.

This device is not intended to provide time sensitive data or alarms. This system may not be used as a substitute for direct medical intervention or emergency care.

Interpretation of the information collected and transmitted requires clinical judgement by an experienced medical professional.

Substantial Equivalence Summary
The TCx-I-DV Remote Care Management system has the same fundamental technology as the predicate devices. Verification activities including substantial equivalence testing demonstrates that this system is substantially equivalent to the predicate devices in terms of functionality and intended use.

Conclusion:
The TCx-I-DV system is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G6(
Silver Spring, MD 20993-0002

BL Healthcare, Inc.
c/o Mr. Daniel W. Lehtonen
Sr. Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Rd, Unit B7
TWINSBURG, OH 44087

FEB - 9 2010

Re: K093379
Trade/Device Name: TCx-I-DV Remote Care Management System
Regulation Number: 21 CFR §876.5860
Regulation Name: High permeability hemodialysis system
Regulatory Class: II
Product Code: KDI
Dated: January 26, 2010
Received: January 27, 2010

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

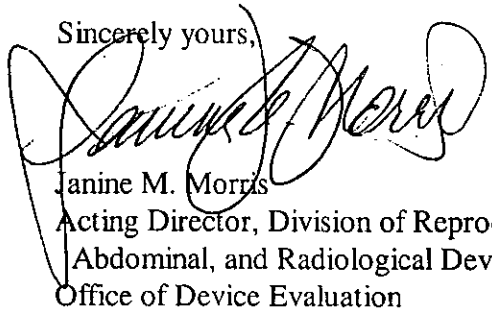
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

BL Healthcare Inc

Statement of Indication of Use

The **TCx-I-DV Remote Care Management system** is for use by patients remotely in combination with a variety of monitoring devices such as blood pressure monitor, NxStage System One Hemo Dialysis system, and weight scale upon the prescription of a licensed physician or healthcare provider. The TCx-I-DV Remote Care Management system serves as the communication link between the compatible devices and the server software at a compatible healthcare facility. The healthcare facility may include healthcare provider, other caregivers, or a disease management center.

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Prescription Use_____X_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K093379